Appliance for percutaneous insertion of connection of pedicle screws has two arms of equal length with transverse connection, circular arm and circular support,

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Abstract

The equilateral triangle is located in a circle with a shared center point. These geometric principles determine the stereotactically guided percutaneous implantation of the lengthwise support connecting the polyaxial pedicle screws without the necessity of prolonged exposure of the spine during an operation. The appliance consists of two arms of equal length with a cross-connection on a plane on which swivels a circular arm of freely selected radius and holding the circular lengthwise support.

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Prüfungsantrag gem. § 44 PatG ist gestellt

(54) Gerät zur stereotaktisch geführten perkutanen Implantation der Längsverbindung der polyaxialen Pedikelschrauben

(57) Die offene transpedikuläre Instrumentierung der Wirbelsäule und die perkutane Schraubenplazierung sind etablierte Operationsmethoden. Doch wurde noch kein Weg einer komplett perkutanen Implantation der Pedikelschrauben und derer Längsverbindung beschrieben.
Er hätte ein geringeres intraoperatives Muskeltrauma, kleineren Blutverlust und eine kürzere Operationszeit zur Folge.
Das Wirkungsprinzip des Gerätes entspricht den Prinzipien eines gleichschenkligen Dreiecks. Es besitzt einen Umkreis, der dessen Ecken schneidet, ähnlich wie die sagittale Krümmung der Lendenwirbelsäule die Eintrittspunkte der zwei Pedikelschrauben durchläuft. Eine Schraubenlängsverbindung gleicht einem Kreisbogen mit einem definierbaren Radius und Mittelpunkt.
Die perkutan auf den Schraubenköpfen sitzenden gleichlangen Kanülen sind zu einer Dreieckverbindung geschlossen, um die der vorgebogene Stab bewegt und perkutan in die Schraubenköpfe hineingeschwenkt wird.
Anwendungsgebiet
Das Instrument setzt an der Basis der Wirbelsäulenchirurgie ein. Viele Indikationen für eine dorsale Zuggurtung ohne Notwendigkeit einer Spinalkanalinzision könnten dadurch ersetzt werden.

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Beschreibung

Der aktuelle Stand der Technik

[0001] Die offene transpedikuläre Instrumentierung der Wirbelsäule ist eine bereits seit Jahrzehnten etablierte Operationsmethode (2–19, 21–28, 32, 34–37, 40–41, 44–47, 49–55, 57–60). Die rasche Entwicklung der wirbelsäulenspezifischen Operationstechnik, der Zugangswege sowie die in den letzten Jahren geradezu explosionsartig gestiegene Zahl der Implantate machen es zwingend erforderlich, auch nach neuen Ideen zu suchen. Die von allen Seiten geförderte chirurgische minimalinvasive Behandlungsphilosophie wird es in der Zukunft verbieten, die häufig nur zur Unterstützung der endgültigen ventralen Instrumentation durchgeführte dorsale Stabilisierung im Sinne einer dorsalen Zuggurtung mittels der herkömmlichen Muskel- und Bandapparat zerstörenden Zugangsweise durchzuführen. Während die die Bauchmuskulatur schonenden allgemeinchirurgischen endoskopischen Zugänge bereits auf breite Zustimmung gestoßen sind und mit großem Können durchgeführt werden, wurden noch keine etablierten Methoden beschrieben, die eine komplette perkutane Implantation der Pedikelschrauben und der Längsträger standardisieren und optimal ermöglichen. Die perkutane Schraubenplazierung ist dagegen seit der Einführung 1984 (1, 20, 29, 30–31, 33 38–39, 42–44, 48, 56) eine anerkannte Methode, die jedoch per definitionem eine externe Verbindung der perkutan implantierten Schrauben zum Ziel hat. Sie hatte längst den Eingang in den klinischen Alltag gefunden, konnte sich dennoch nicht weit verbreiten, da sich die Handhabung der extrakorporalen Montage als recht problematisch erwiesen hat. Die Befürworter dieser Technik hatten allerdings diverse Verfahren entwikkelt, die eine anatomisch belegbare und standardisiert sichere Plazierung der Pedikelschrauben ermöglichen (29–30, 39, 43–44, 48, 56). Die Fehlplazierungsrate wurde dadurch minimalisiert und gleicht einer offenen Schraubenimplantation.

[0002] Bei der bereits seit mehreren Jahren beschriebenen Methodik der perkutanen Schraubenimplantation war es bis dato offensichtlich nicht möglich, die Schraubenköpfe im gleichen (perkutanen) Arbeitsgang mit den Stäben zu verbinden. Erst eine rein perkutane vollständige Wirbelsäuleninstrumentation einschließlich Montage der schraubenverbindenden Längsträger würde einen weiteren Schritt auf dem Gebiet der Minimalisierung des iatrogenen Traumas bedeuten. Dieses Problem wird durch die im Patentanspruch aufgeführten Geräteeigenschaften gelöst.

[0003] Das Wirkungsprinzip des Gerätes leitet sich aus den einfachen geometrischen Prinzipien ab (Zeichnung 1, 2). Jedes Dreieck hat einen Umkreis, dessen Mittelpunkt innerhalb dieses Dreiecks liegt und alle 3 Ecken schneidet. Der Mittelpunkt des Umkreises ist der Schnittpunkt der Mittelsenkrechten. In einem gleichschenkligen Dreieck liegt der Mittelpunkt des Umkreises in der Symmetrieachse des Dreiecks (45). Die sagittale Krümmung der Lendenwirbelsäule beschreibt einen Kreis, bzw. ein Oval. Gemessen an den Eintrittspunkten der zwei Pedikelschrauben eines oder mehrerer Bewegungssegmente, werden diese durch den Kreis geschnitten (Zeichnung 2, 3). Somit ist der ein Schraubenpaar verbindende Stab geometrisch gesehen bei vorgegebener Krümmung ein Kreisbogen mit einem definierbaren Radius und Mittelpunkt.

[0004] Die perkutan auf den Schraubenköpfen sitzenden Kanülen sind gleich lang. Durch eine Brücke werden sie zu einer Verbindung geschlossen, die geometrisch betrachtet einem gleichschenkligen Dreieck entspricht. Dieses Dreieck und der Umkreis besitzen somit den gleichen Mittelpunkt, um den auf einem Schwenkstab sitzender und die Pedikelschrauben zu verbindender Längsträger gegebenenfalls bewegt werden kann (im Kreis an einem festen Arm) (Zeichnung 3). Eine vorgegebene Längsträgerkrümmung ist daher die Voraussetzung für eine derartige Implantation. Diese muss industriell gewährleistet sein, und beträgt etwa 18 cm. Folgt die Krümmung (Radius) der Wirbelsäule einem Kreis nicht, ist die Dreieckkonstruktion alleine durch eine entsprechende Schraubenpositionierung und Ankippung der beweglichen polyaxialen Schraubenköpfe zur Aufnahme des kreisförmig vorgebogenen Stabes möglich.

[0005] Das Prinzip der gänzlich perkutanen Wirbelsäuleninstrumentierung stützt sich auf die bereits im Vorfeld erarbeiteten Techniken der perkutanen Schraubenimplantation (1, 20, 29, 30–31, 33 38–39, 42–44, 48, 56) Nach Erfassung der Pedikeleintrittspforte unter dem C-Bogen oder aber unterstützt mit der spinalen Navigation, beginnt die perkutane Instrumentation des Pedikels mit einem Kirschnerdraht. Danach folgt der eigentliche Hautschnitt – jeweils etwa 18 mm pro 1 Schraube. Über den im Pedikel liegenden Kirschnerdraht werden sukzessive Dehnungskanülen bis zum Erreichen eines entsprechend weiten Arbeitskanals eingebracht. Dieser wird mit einer Platzhaltekanüle festgehalten, die wiederum auch mit einem Fixierarm optional gehalten werden kann. Diese Kanüle ist bereits ein Teil des Stabeinführsystems, später "Karussell" genannt. Der Pedikel wird nun entweder mit dem üblichen lumenhaltigen Bohrer aufgebohrt und dann nach Entfernung des Kirschnerdrahtes mit einer standardmäßigen polyaxialen Schraube versehen. Dieser Vorgang wäre auch nach vorausgegangenem Gewindeschneiden (kanülierter Gewindeschneider) möglich. Über den Kirschnerdraht wird ebenso eine kanülierte polyaxiale Pedikelschraube eingeführt. Die erste Option ermöglicht die Benutzung der Standardimplantate, jedoch mit der Gefahr den Schraubenkanal durch eine unkontrollierte Verschiebung der Arbeitskanüle zu verlieren. Die zweite Möglichkeit bedarf der Spezialimplantate (perforierte polyaxiale Schrauben), jedoch in Kombination mit der spinalen Navigation bietet sie eine relevant kürzere Durchleuchtungszeit. Eine Durchleuchtung ist nur am Anfang zur Positionierung des Kirschnerdrahtes notwendig. Liegt dieser korrekt, erfolgen weitere Schritte ohne Notwendigkeit einer ausgiebigen Röntgenkontrolle.

[0006] Wünschenswert ist eine leicht (5–10 Grad) konvergierende oder aber weitgehend parallele Positionierung der einseitigen Schraubenpaare.

[0007] Die Schraube wird durch die Arbeitskanüle eingebracht, wobei der Schraubenkopf mit einem Instrument (Zeichnung 4) festgehalten und positioniert wird. Das Instrument wird in der Arbeitskanüle durch eine in seiner Wand eingefrästen Führung eingebracht, so dass das Übereinanderliegen der seitlichen Schraubenöffnung und der auf dem Schraubenkopf sitzenden Kanüle, die ebenso im Bereich des Schraubenkopfes eine seitliche Öffnung besitzt, gewährleistet ist. Diese Vorgänge werden einseitig an der oberen und unteren Schraube durchgeführt. Auf die nach außen (extrakutan) hin verlängerten Implantate wird das eigentliche Stabeinführinstrument aufgesetzt (Zeichnung 5).

[0008] Das eigentliche Instrument besteht aus zwei Aufsätzen, die auf die Arbeitskanülen aufgesteckt werden. Sie sind mit der Brücke verbunden, auf welcher der bewegliche Arm fixiert ist (Zeichnung 5). Da der interpedikuläre Abstand nicht konstant ist, ist auch eine stufenlose Verstellung und Arretierung des Kanülenabstandes notwendig. Bei Veränderung des interpedikulären Abstandes ändert sich aber auch der Winkel der Kanülen zueinander, da die Ausrichtung der frei beweglichen Schraubenköpfe der Krümmung des festgelegten Radius des Längsträgers zwangsläufig fol-

gen muss. Damit das geometrische Prinzip eines gleichschenkligen Dreiecks im Umkreis greift, müssen die auf den Schraubenköpfen sitzenden Arbeitskanülen samt der Aufsätzen bewegbar bzw. kippbar sein. Durch ein Zahnradprinzip sind die auf den Schraubenkanülen steckenden Aufsätze verbunden, was ihre gleichmäßige Ankippung bei Abstand- und Winkelveränderung der Schraubenköpfe bedingt und der Erhaltung der geometrischen Grundsätze des gleichschenkligen Dreiecks dient.

[0009] Sitzt das Karussell auf den Pedikelschrauben, wird der vorgebogene Stab perkutan in die Schraubenköpfe über den beweglichen Arm hineingeschwenkt und mit der Innenmutter leicht fixiert.

[0010] Zur Verringerung des Gewebswiederstandes am Stabanfang muss diese entsprechend angespitzt sein.

[0011] Damit eine derartige Instrumentation durchgeführt werden kann, sind vier Hautinzisionen von etwa 18 mm Länge zur Einbringung der Pedikelschrauben, zwei Inzisionen von der Länge etwa 6–7 mm zur perkutanen Implantation der Längsträger nötig. Eine Fasciennaht ist bei dem Hautverschluss nicht zwingend erforderlich.

[0012] Das Gerät lässt sich mit geringfügigen Veränderungen an jede derzeit erhältliche polyaxiale Pedikelschraube/Schraubensystem anwenden.

Vorteile

[0013] Erst eine rein perkutane vollständige Stabilisierung einschließlich Montage der schraubenverbindenden Längsträger würde einen weiteren Schritt auf dem Gebiet der Minimalisierung des iatrogenen Traumas bei einer einfachen dorsalen Wirbelsäuleninstrumentation bedeuten. Sie könnte die Vorzüge und manche Indikationen der offenen und der perkutanen Schraubenimplantation vereinigen und bei weiterer Entwicklung die Behandlungsphilosophie in einem bestimmten Grad verändern. Die Vorteile liegen auf der Hand: Das intraoperative Muskeltrauma ist wesentlich kleiner, da ein echtes Muskelablösen zur Freilegung der Wirbelsäule nicht mehr nötig ist, nach entsprechender Lernkurve bedeutend kürzere Operationszeit. Effekte wie zum Beispiel wesentlich kleinere postoperative Narbe oder auch höhere Akzeptanz durch die Patienten durch das wesentlich kleinere Ausmaß des Eingriffs sind medizinisch gesehen von kleinerer Bedeutung. Die von der periduralen endoskopischen Bandscheibenchirurgie bekannte schnellere postoperative Mobilisation der Patienten im Vergleich zu der klassischen, auch mikroskopischen Operationsmethode, kommen bei offenem Zugang zur Wirbelsäulenimplementierung und der um ein Mehrfaches größeren Zugangslänge hier um so deutlicher zum Tragen.

[0014] Es resultiert daraus ein zu vernachlässigender Blutverlust sowie ein minimales Muskeltrauma, da die Muskelfasern nicht durchtrennt sondern auseinandergedrängt werden. Die bloßliegenden Muskelfasern verschließen sofort den Zugangstunnel, Blutungen oder grobe Läsionen des Muskelgewebes sind eher eine Seltenheit. Die traumabedingten postoperativen Schmerzen werden dadurch wesentlich reduziert, die Mobilisation des Patienten erfolgt früher.

Mögliche Einsetzbarkeit

[0015] Das Instrument setzt an der Basis der transpedikulären Wirbelsäuleninstrumentation ein und ist demnach keine hochspezifische Entwicklung für besondere Fragestellungen in der Wirbelsäulenchirurgie. Auf diese Weise wäre die potentielle Einsetzbarkeit durch den ohnehin weiten Anwenderkreis entsprechend hoch. Theoretisch könnte man damit in der Zukunft die meisten Indikationen für eine dorsale Zuggurtung ohne Notwendigkeit einer Spinalkanalinzision vollkommen ersetzen, da mit den herkömmlichen Implantaten zuzüglich des o. g. Instrumentes eine einfache und viel schonendere Option der dorsalen Stabilisierung gewährleistet wäre.

[0016] Die Integration der zusätzlichen Schrauben (mehr als 2 Schrauben in einer Reihe) in das Instrument scheint auf jeden Fall möglich zu sein, bedarf jedoch einer präziseren Implantation der Schraubenlage in der mit dem Stab zu versorgenden Reihe. Die mittleren Schrauben müssen entsprechend tiefer zu liegen kommen; die primäre Verwendung der sog. Langkopfschrauben könnte von Vorteil sein. Damit wären auf diese Weise die leichteren Formen der Spondylolisthesen (Meyerding 1 bis 2) ohne eine nennenswerten Spinalkanalstenose schonend zu versorgen, vorausgesetzt, eine ventrale Abstützung folgt. Eine peridurale endoskopisch unterstützte Dyscektomie mit nachfolgendem Zwischenwirbelraumersatz sind beim rein dorsalen Zugang denkbar. Die Instrumentation der Brustwirbelsäule ist monosegmental bis bisegmental möglich. Zu bedenken ist jedoch eine etwas höhere Position der Schraubenköpfe, damit ein Konflikt des Längsträgers mit dem Wirbelsäulenabschnitt zwischen den Pedikelschrauben vermieden wird.

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Patentansprüche

1. Gerät zur stereotaktisch geführten perkutanen Implantation der Längsverbindung der Pedikelschrauben, **dadurch gekennzeichnet**, dass durch Einhaltung der bestimmten geometrischen Prinzipien des gleichschenkligen Dreiecks in einem Umkreis mit gemeinsamen Mittelpunkt, die die Gerätekonstruktion charakterisieren, eine stereotaktisch geführte perkutane (geschlossene) Implantation des die polyaxialen Pedikelschrauben verbindenden Längsträgers ohne Notwendigkeit einer langstreckigen operativen Freilegung der Wirbelsäule möglich ist.

2. Das Gerät nach Patentanspruch 1, dadurch gekennzeichnet, dass das Gerät aus zwei gleich langen Armen, mit einer Querverbindung in einer Ebene zusammengeschlossen, zusammengesetzt ist, auf der ein schwenkbarer, zu einem Kreis von einem frei bestimmbaren Radius gebogener Arm, zur Aufnahme des ebenso kreisförmig gebogenen Längsträgers aufgesetzt ist, der perkutan eingeführt wird. Die Köpfe der zuvor perkutan in die Wirbelsäule eingebrachten polyaxialen Pedikelschrauben werden dabei in einer Ebene aufgerichtet und können bedingt durch die Gerätemerkmale entlang des Längsträgers bis zu einem Grad gleichmäßig zu- oder auseinander bewegt werden, wodurch eine Kompression und Distraktion der Wirbel erzielt wird.

3. Das Gerät nach Patentanspruch 1, dadurch gekennzeichnet, dass – bedingt durch die Gerätekonstruktion – die in einer Ebene erzwungene Position der Schraubenköpfe eine gleichzeitige perkutane Verbindung von mehr als einem Schraubenpaar ermöglicht.

Hierzu 5 Seite(n) Zeichnungen

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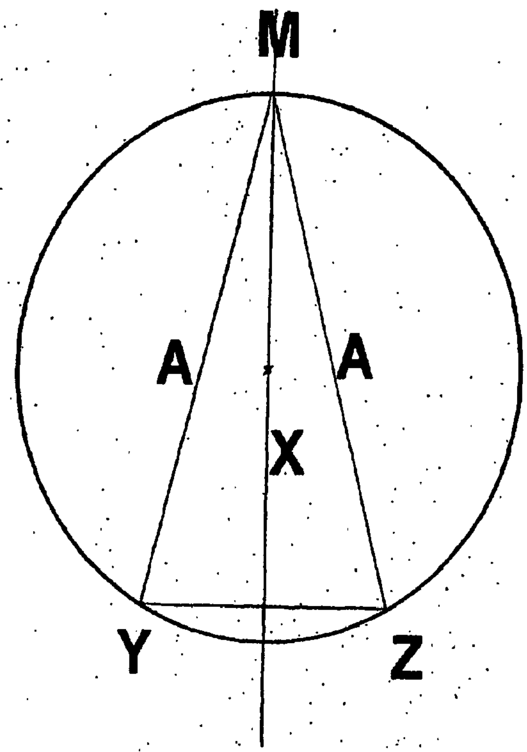
Zeichnung 1

Gleichschenkliges Dreieck in einem Umkreis



A = A
X- Dreieck / Umkreismittelpunkt
YZ- Kreisbogen
M- Symmetrieachse

Gerät zur stereotaktisch geführten perkutanen Implantation der Längsverbindung der polyaxialen Pedikelschrauben.

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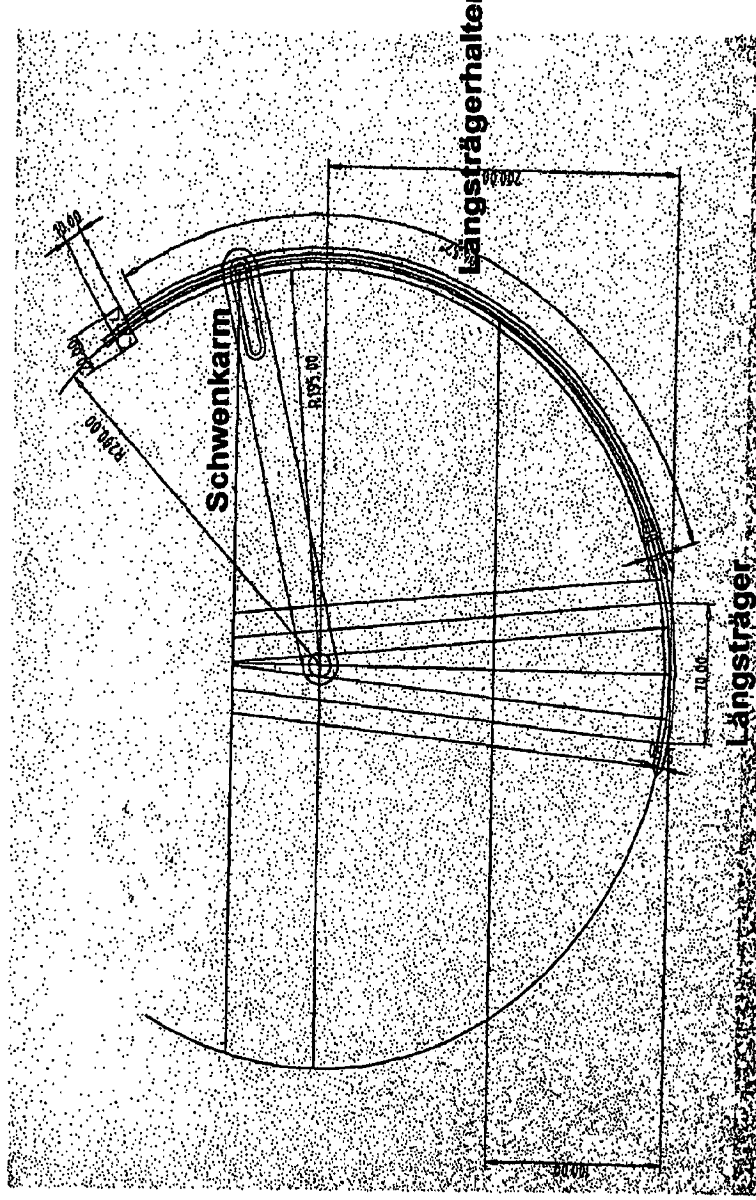
Zeichnung 2



Gerät zur stereotaktisch geführten perkutanen Implantation der Längsverbindung der polyaxialen Pedikelschrauben.

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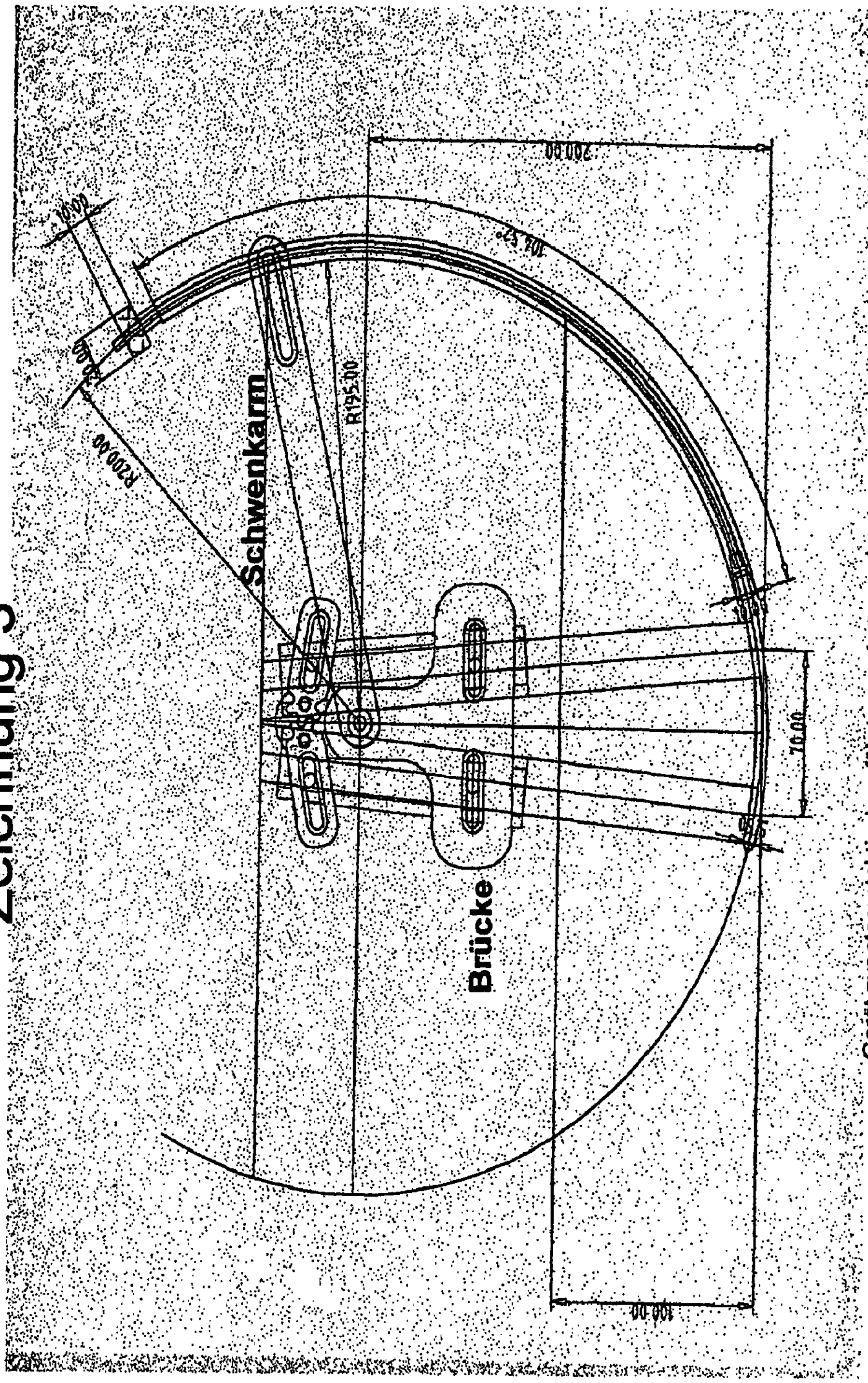
Zeichnung 3



Gerät zur stereotaktisch geführten perkutanen Implantation der Längsverbindung der polyaxialen Pedikelschrauben.

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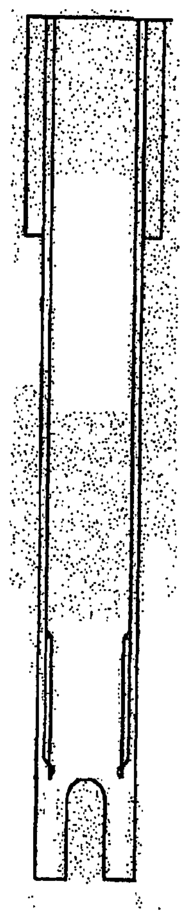
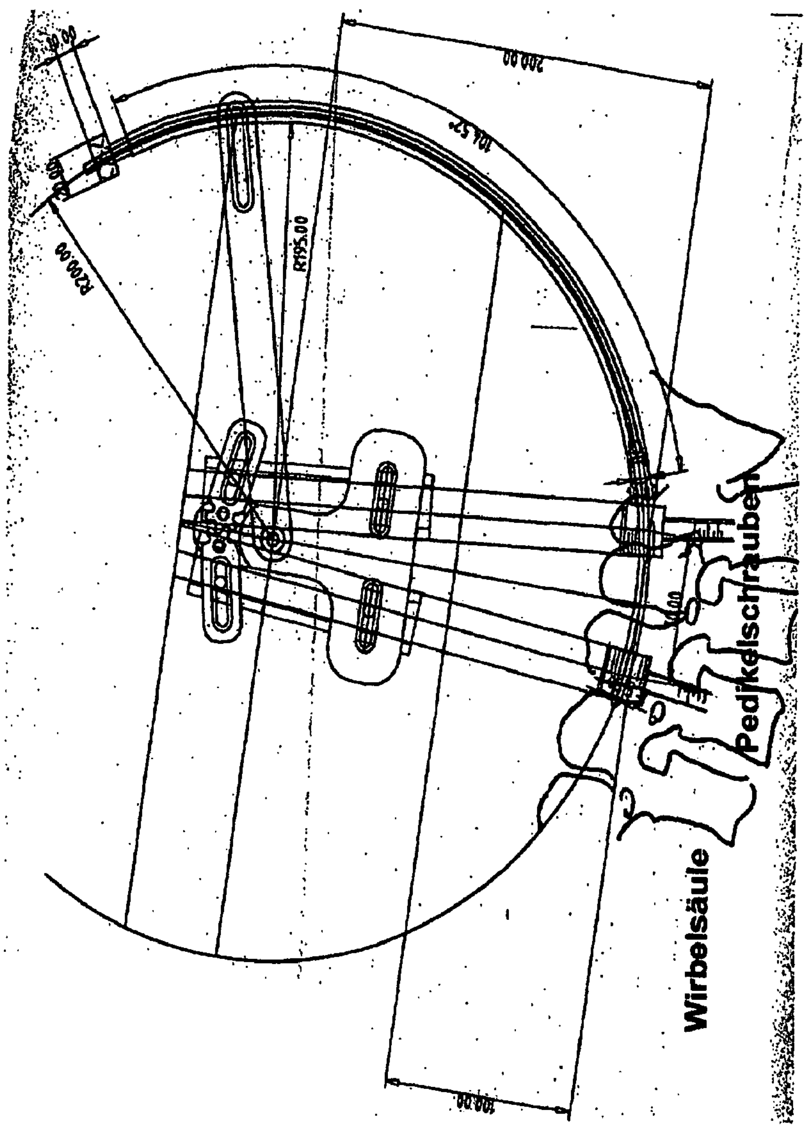
Zeichnung 4



Gerät zur stereotaktisch geführten perkutanen Implantation der Längsverbindung der polyaxialen Pedikelschrauben.

Zeichnung 5



Gerät zur stereotaktisch geführten perkutanen Implantation der Längsverbindung der polyaxialen Pedikelschrauben.

FEDERAL REPUBLIC OF GERMANY

Unexamined Laid-Open Patent Application
DE 100 27 988 A 1

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DEUTSCHES PATENT-UND MARKENAMT (GERMAN PATENT AND TRADEMARK OFFICE)

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DE 297 03 947 U 1

The following information was taken from the documents submitted by the Applicant

Examination Request submitted acc. to § 44 PatG (German Patent Law)

Device for stereotactically guided percutaneous implantation of the longitudinal connectors of polyaxial pedicle screws.

Open transpedicular instrumentation of the spine and percutaneous screw placement are established operating techniques. However, up to this date no method has been specified for a completely percutaneous implantation of pedicle screws and their longitudinal connectors.
Such a technique would reduce intraoperative muscle trauma, blood loss, and surgery time.
The device's principle of operation corresponds to the principles of an isosceles triangle. Its circumcircle crosses its corners, similar to the sagittal bend of the lumbar spine crossing the entrance points of the two pedicle screws. A longitudinal screw connector is comparable to a circular arc with a definable radius and center point.
The equally long cannulas seated percutaneously on the screw heads close to a triangular connection, around which the pre-bent rod is moved and tilted percutaneously into the screw heads.
Area of Application
The instrument's area of application starts at the base of lumbar spine surgery. This allows replacement of many indications for dorsal tension band wiring without the need of a spinal canal incision.

Specification

Prior Art

[0001] Open transpedicular instrumentation of the spine has been an established operating technique for several decades (2-19, 21-28, 32, 34-37, 40-41, 44-47, 49-55, 57-60). Rapid development of spine-specific operating techniques, new access routes, and the almost explosive increase in the number of implants dictate the search for new ideas. Wide-spread support for minimum invasive surgical treatment philosophy will eventually forbid dorsal stabilization often used to assist the final ventral instrumentation by dorsal tension band wiring using conventional muscle and ligament destroying access routes. While general surgical endoscopic accesses that are gentle to the pelvic muscles have become widely accepted and are performed with great skill, no established techniques have been specified to provide a standard and to allow optimum completely percutaneous implantation of pedicle screws and longitudinal connectors. However, percutaneous screw placement is an accepted technique since its introduction in 1984 (1, 20, 29, 30-31, 33 38-39, 42-44, 48, 56), but according to definition its objective is an external connection of the percutaneously implanted screws. Even though it has been accepted in clinical environments its use never spread, since extracorporeal mounting proved to be rather problematic. Supporters of this technique developed various procedures that allow an anatomically documented and standardized safe pedicle screw placement (29-30, 39, 43-44, 48, 56). This resulted in a minimized malposition rate and is similar to an open screw implantation.

[0002] To this date, the percutaneous screw implantation technique that has been specified for several years has not provided a solution for connection of the screw heads with the rods in one (percutaneous) process. Only a purely percutaneous complete spinal instrumentation including mounting of the longitudinal screw connectors would represent another step forward in regards to minimizing iatrogenous trauma. This problem will be solved by the device characteristics specified in the patent claim.

[0003] The device's principle of action is based on simple geometric principles (drawing 1, 2). Every triangle has a circumcircle with a center point inside the triangle, whereby the circumcircle crosses all 3 corners. The center point of the circumcircle is the intersection of the apothem. In an isosceles triangle, the circumcircle's center point lies on the triangle's axis of symmetry (45). The sagittal bend of the lumbar spine describes a circle or an oval. Measured at the entrance points of the two pedicle screws of one or more movement segments, these points are crossed by the circle (drawing 2, 3). In geometrical terms, the rod connecting the two screws is a circular arc with a definable radius and center point at a predetermined bend.

[0004] The cannulas seated percutaneously on the screw heads are of equal length. A bridge closes them to provide a connection that corresponds geometrically to an isosceles triangle. This triangle and its circumcircle have the same center point around which a longitudinal connector seated on a swivel rod can be moved for pedicle screw connection (in a circle on a fixed arm) (drawing 3). This type of implantation requires a predetermined longitudinal connector bend. This must be warranted on an industrial level and should be about 18 cm. If the bend (radius) of the spine does not follow a circle, the triangle construction can be achieved by corresponding screw placement and tilting of the movable polyaxial screw heads for mounting of the circular preshaped rod.

[0005] The principle of completely percutaneous spine instrumentation is based on previously developed techniques for percutaneous screw implantation (1, 20, 29, 30-31, 33 38-39, 42-44, 48, 56). After locating the pedicle entrance point under the C-arm or with the support of spinal navigation, percutaneous instrumentation of the pedicle is started using a K-wire. Then, the actual skin laceration is performed - about 18 mm per 1 screw. Above the K-wire inside the pedicle, expanding cannulas will be inserted successively until an appropriately wide working canal has been established. This canal is held in place by a placeholder cannula which in turn may be held by a fixing arm (optional). This cannula is part of the rod introducer system which will be referred to as "carousel" later on. Then, the pedicle will be drilled open using a standard lumen-type drill and after removal of the K-wire it will be provided with a standard polyaxial screw. This process could also be performed after previous tapping (cannulated drill). Additionally, a cannulated polyaxial pedicle screw will be

introduced over the K-wire. The first option allows use of standard implants, however, it also bears the risk that an uncontrolled shift of the working cannula will result in the loss of the screw canal. The second option requires special implants (perforated polyaxial screws), but in combination with spinal navigation it allows for a relatively shorter fluoroscopy time. Fluoroscopy is only necessary at the beginning for K-wire positioning. Once the K-wire is positioned correctly, the following steps can be performed without extensive fluoroscopy.

[0006] Preferably, the one-sided screw pairs should be positioned at a slight convergence (5-10 degrees) or an overall parallel position.

[0007] The screw will be introduced through the working cannula, whereby the screw head will be held and positioned with an instrument (drawing 4). The instrument will be introduced into the working cannula through a guideway cut into its wall in order to ensure that the lateral screw holes and the cannula seated on the screw head, which also has a lateral opening in the area of the screw head, are positioned on top of each other. These procedures are performed on one side at the upper and lower screw. The actual rod introducer instrument will be placed on the implant which extends towards the outside (extracutaneous) (drawing 5).

[0008] The actual instrument consists of two attachments that will be plugged onto the working cannulas. They are connected with the bridge on which the movable arm is fixated (drawing 5). Since the interpedicular distance is not constant, infinitely variable adjustment and locking of the cannula spacing is required. Any change of the interpedicular spacing results in a change of the angle between the cannulas, since the alignment of the freely movable screw heads must positively follow the bend of the defined longitudinal connector radius. In order to realize the geometric principle of an isosceles triangle in its circumcircle, the working cannulas seated on the screw heads must be movable and/or tiltable. The attachments plugged onto the screw cannulas are connected by gears which affect their uniform tilting during screw head spacing and angle changes and ensure that the geometric principles of an isosceles triangle are maintained.

[0009] Once the carousel is seated on the pedicle screws, the pre-bent rod swivels via the movable arm percutaneously into the screw heads and is lightly fastened with the inside nut.

[0010] In order to reduce tissue resistance at the start of the rod, the rod must be tapered accordingly.

[0011] The completion of this type of instrumentation requires four about 18 mm long skin incisions for insertion of the pedicle screws, and two incisions with a length of about 6 to 7 mm for percutaneous implantation of the longitudinal connectors. Fascia sutures are not absolutely required for skin closure.

[0012] With minor modifications, this device can be used for any polyaxial pedicle screws/screw system currently available.

Benefits

[0013] Only a purely percutaneous complete stabilization including mounting of the longitudinal screw connectors would represent another step forward in regards to minimizing iatrogenous trauma during basic dorsal lumbar spine instrumentation. It could combine the benefits of some indications of open and percutaneous screw implantation and upon further development change the treatment philosophy to a certain degree. The benefits are obvious: The intraoperative muscle trauma is significantly reduced, since muscles will not have to be detached in order to expose the lumbar spine; plus after an appropriate learning curve, surgery time will be significantly shortened. Effects like significantly smaller post-surgery scars, or better patient acceptance due to the significantly less severe invasion are of lesser medical significance. The quicker post-surgery mobilization of patients known from peridural endoscopic intervertebral disk surgery in comparison to the classical or microscopic surgery technique will be even more significant with the open access to the lumbar spine implementation and the multiple times longer access length.

[0014] The result is a negligent blood loss and minimum muscle trauma, since muscle fibers will not be severed but merely displaced. The exposed muscle fibers immediately close the access tunnel; bleeding or rough lesions of the muscle tissue are very rare. Trauma-related post-surgery pain is reduced significantly; mobilization of the patient will occur sooner.

Possible Applications

[0015] The instrument is used at the base of transpedicular lumbar spine instrumentation, and therefore, it is not a highly specific development for particular issues in lumbar spine surgery. Therefore, the potential area of application is respectively high as this presents an already wide user base. Theoretically, most indications for dorsal tension band wiring could be replaced completely in the future without the necessity of spinal canal incision, since a simple and much less invasive option for dorsal stabilization could be ensured with conventional implants and the described instrument.

[0016] Integration of additional screws (more than 2 screws in a row) into instrument seems to be absolutely possible, however, it will require a more precise implantation of the screw position in the row to be served by the rod. The center screws must be accordingly deeper; primary use of so-called oblong head screws could be beneficial. This would allow gentle care of lighter forms of spondylolistheses (Meyerding 1 to 2) without any notable spinal canal stenosis, provided a ventral support is provided. A peridural endoscopically supported dyscectomy with subsequent intervertebral space replacement are feasible with a purely dorsal access. Instrumentation of the thoracic spine is feasible monosegmental to bisegmental. However, a slightly higher position of the screw heads should be considered in order to avoid any conflict between the longitudinal connector and the spine section between the pedicle screws.

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Patent Claims

1. Device for stereotactically guided percutaneous implantation of the longitudinal connectors of pedicle screws, **characterized by** the adherence to certain geometrical principles of an isosceles triangle within a circumcircle with shared center point characterizing the device construction, a stereotactically guided percutaneous (closed) implantation of the longitudinal connector that connects the polyaxial pedicle screws without the necessity to provide a long surgical opening to expose the spine.
2. The device according to Claim 1, characterized by the device consisting of two equally long arms that are connected at one level by a transverse connection, with a swivelling arm that is bent to a freely definable radius for mounting the longitudinal connector which has the same circular shape and will be introduced percutaneously. The heads of polyaxial pedicle screws that were previously inserted into the spine will be aligned at one level and due to the device characteristics can be uniformly moved apart or towards each other up to a certain degree, resulting in the compression or distraction of the vertebra.
3. The device according to Claim 1, characterized by the forced screw head position at one level – due to the device construction – allowing the simultaneous percutaneous connection of more than one pair of screws.

See 5 Page(s) of drawings

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Drawing 1

Isosceles Triangle in a Circumcircle

A=A
X- Triangle / Circumcircle Center Point
YZ- Circular Arc
M- Axis of Symmetry

Device for stereotactically guided percutaneous implantation of the longitudinal connectors of polyaxial pedicle screws.

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Drawing 2

[Schwenkarm]
Swivel arm

[Langsträgerhalterung]
Longitudinal connector mount

[Längsträger]
Longitudinal connector

Device for stereotactically guided percutaneous implantation of the longitudinal connectors of polyaxial pedicle screws.

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Drawing 3

[Schwenkarm]
Swivel arm

[Brücke]
Bridge

Device for stereotactically guided percutaneous implantation of the longitudinal connectors of polyaxial pedicle screws.

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Drawing 4

Device for stereotactically guided percutaneous implantation of the longitudinal connectors of polyaxial pedicle screws.

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Drawing 5

[Wirbelsäule]
Spine

[Pedikelschrauben]
Pedicle screws

Device for stereotactically guided percutaneous implantation of the longitudinal connectors of polyaxial pedicle screws.

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Patent Specifications
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Publications considered for evaluation of patentability:
DE 297 03 947 U1

Device for stereotactically guided percutaneous implantation of the longitudinal connectors of pedicle screws

Device for stereotactically guided percutaneous implantation of the longitudinal connectors of pedicle screws, characterized by a bridge with at least two attachments with infinitely variable spacing for mounting two equally long working cannulas which sit on the pedicle screw heads after the pedicle screws have been fastened, and by a swivel arm in a pivot on the bridge above the variable attachments which has a mount at its free end for a semi-circular longitudinal connector that is provided for the longitudinal connection of the pedicle screws, whereby the pivot above the bridge is arranged in a way where the semi-circular longitudinal connector at the free end of the swivel arm will move through both pedicle screw heads when the swivel arm is swiveled.

A=A
X- Triangle / Circumcircle Center Point
YZ- Circular Arc
M- Axis of Symmetry

Specification

[0001] The invention concerns a device for stereotactically guided percutaneous implantation of the longitudinal connectors of pedicle screws. Its area of application starts at the base of lumbar spine surgery and may replace many indications for dorsal tension band wiring without requiring any spinal canal incision. The device can be adapted for any currently available polyaxial pedicle screws/screw systems.

[0002] Open transpedicular instrumentation of the lumbar spine has been an established surgery technique for many years. Rapid development of spine-specific operating techniques, new access routes, and the almost explosive increase in the number of implants dictate the search for new ideas. Wide-spread support for minimum invasive surgical treatment philosophy will eventually forbid dorsal stabilization often used to assist the final ventral instrumentation by dorsal tension band wiring using conventional muscle and ligament destroying access routes. While general surgical endoscopic accesses that are gentle to the pelvic muscles have become widely accepted and are performed with great skill, no established techniques have been specified to provide a standard and to allow optimum completely percutaneous implantation of pedicle screws and longitudinal connectors. However, percutaneous screw placement is an accepted technique since its introduction in **1984**, but according to definition its objective is an external connection of the percutaneously implanted screws. Even though it has been accepted in clinical environments its use never spread, since extracorporeal mounting proved to be rather problematic.

[0003] To this date, the percutaneous screw implantation technique that has been specified for several years has not provided a solution for connection of the screw heads with the rods in one (percutaneous) process. Only a purely percutaneous complete spinal instrumentation including mounting of the longitudinal screw connectors would represent another step forward in regards to minimizing iatrogenous trauma.

[0004] DE 297 03 947 U1 specifies a device for percutaneous pedicle screw placement, in particular for percutaneous pedicle screw placement and/or vertebra fusion. The spine is blocked in one movement element at the rear section of the spine. To achieve this, screws are placed percutaneously in the vertebra alternating between medial and lateral. For the completion of screw placement, the specified device will be fixated to a spine section that is not involved in the actual procedure. The screws placed with the assistance of this device will not affect a complete blockage of the spine, since a certain movement range will be maintained in the front section of the spine. Then the initially pain-free section of the spine will become sensitive again. Therefore, this procedure only can be used as diagnostic procedure prior to further intervention for disk replacement.

[0005] This invention has the objective to create a device for percutaneous implantation of the pedicle screws' longitudinal connector.

[0006] This objective is met by patent claim 1. The invented device for stereotactically guided percutaneous implantation of the longitudinal connectors of pedicle screws is characterized by a bridge with at least two attachments with infinitely variable spacing for mounting two equally long working cannulas which sit on the pedicle screw heads after the pedicle screws have been fastened, and by a swivel arm in a pivot on the bridge above the variable attachments which has a mount at its free end for an arched longitudinal connector that is provided for the longitudinal connection of the pedicle screws, whereby the pivot above the bridge is arranged in a way where the arched longitudinal connector at the free end of the swivel arm will move through both pedicle screw heads when the swivel arm is swiveled. Preferably, the pedicle screws should be perforated polyaxial screws.

[0007] Additional preferred embodiments are specified in the dependant claims. An instrument for insertion of the pedicle screws is the subject of Claim 4.

[0008] The device for stereotactically guided percutaneous implantation of the pedicle screws' longitudinal connector has two attachments that are plugged onto the working cannulas. They are connected with the bridge on which the movable arm is fixated. Since the interpedicular distance is not constant, infinitely variable adjustment and locking of the cannula spacing is required. Any change of the interpedicular spacing results in a change of the angle between the cannulas, since the alignment of the freely movable screw heads must positively follow the bend of the defined longitudinal connector radius. In order to realize the geometric

principle of an isosceles triangle in its circumcircle, the working cannulas seated on the screw heads must be movable and/or tiltable. The attachments are connected by gears which affect their uniform tilting during screw head spacing and angle changes and ensure that the geometric principles of an isosceles triangle are maintained. Once the carousel is seated on the pedicle screws, the pre-bent longitudinal connector swivels via the movable arm into the screw heads and is fastened with the inside nut.

[0009] Integration of more than two screws in one row in the instrument for stereotactically guided percutaneous implantation of the pedicle screws' longitudinal connectors is possible in any case, if the pedicle screws have been implanted with high precision so they can be caught by the arched longitudinal connector. The center pedicle screw must be accordingly lower. The use of so-called oblong head screws could be beneficial. This would allow gentle care of lighter forms of spondylolistheses (Meyerding 1 to 2) without any notable spinal canal stenosis, provided ventral support is provided. A peridural endoscopically supported dyscectomy with subsequent intervertebral space replacement are feasible with a purely dorsal access.

[0010] In order to reduce tissue resistance, the longitudinal connector should be tapered accordingly.

[0011] The principle of operation of this device for stereotactically guided percutaneous implantation of the pedicle screws' longitudinal connector is derived from the geometric principle that each triangle has a circumcircle, whereby its center point lies within the triangle and serves as intersection of the apothem an the triangle sides. The circumcircle crosses all corners of the triangle. In an isosceles triangle, the circumcircle's center point lies on the triangle's axis of symmetry.

The sagittal bend of the lumbar spine describes a semi-circle or part of an oval. Measured at the entrance points of the two pedicle screws of one or more movement segments, these points are crossed by the circle. In geometrical terms, the rod connecting the two screws is a circular arc with a definable radius and center point at a predetermined bend. The cannulas seated percutaneously on the screw heads are of equal length. A bridge closes them to provide a connection that corresponds geometrically to an isosceles triangle. This triangle and its circumcircle share the same center point around which a longitudinal connector seated on the free end of a swivel arm can be moved for pedicle screw connection. This type of implantation requires a predetermined longitudinal connector bend. If the bend of the spine does not follow a circle, the triangle construction can be achieved by corresponding screw placement and tilting of the movable polyaxial screw heads for mounting of the circular preshaped longitudinal connector.

[0012] After locating the pedicle entrance point under the C-arm or with the support of spinal navigation, percutaneous instrumentation of the pedicle is started using a K-wire. Then, the actual skin laceration is performed - about 18 mm per screw. Above the K-wire inside the pedicle, expanding cannulas will be inserted successively until an appropriately wide working canal has been established. This canal is held in place by a placeholder cannula which in turn may be held by a fixing arm. This cannula is part of the rod introducer system also known as "carousel". Then, the pedicle will be drilled open using a standard lumen-type drill and after removal of the K-wire it will be provided with a standard polyaxial screw. This process could also be performed after previous tapping (cannulated drill). Additionally, a cannulated polyaxial pedicle screw will be introduced over the K-wire. The first option allows use of standard implants, however, it also bears the risk that an uncontrolled shift of the working cannula will result in the loss of the screw canal. For the second option special implants (perforated polyaxial screws) are required. In combination with spinal navigation, relatively short fluoroscopy times are made possible. Fluoroscopy is only necessary at the beginning for K-wire positioning. Once the K-wire is positioned correctly, the following steps can be performed without extensive fluoroscopy.

[00013] Preferably, the one-sided screw pairs should be positioned at a slight convergence (5-10 degrees) or an overall parallel position (on the sagittal plane).

[00014] The screw will be introduced through the working cannula, whereby the screw head will be held and positioned with an instrument for which a solution has been provided also. The instrument will be introduced into the working cannula through a guideway cut into its wall in order to ensure that the lateral screw holes and the cannula seated on the screw head, which also has a lateral opening in the area of the screw head, are positioned on top of each other. These procedures are performed on one side at the upper and lower screw. The

actual device for stereotactically guided percutaneous implantation of the pedicle screws' connector will be placed on the implants which extend towards the outside (extracutaneous).

[0015] The completion of this type of instrumentation requires four about 18 mm long skin incisions for insertion of the pedicle screws, and two incisions with a length of about 6 to 7 mm for percutaneous implantation of the longitudinal connectors. Fascia sutures are not absolutely required for skin closure.

[0016] The major advantage of this device for stereotactically guided percutaneous implantation of the pedicle screws' connector is that intraoperative muscle trauma is significantly reduced, since muscles will not have to be detached in order to expose the spine. Plus after an appropriate learning curve, surgery time will be significantly shortened. Effects like significantly smaller post-surgery scars, or better patient acceptance due to the significantly less severe invasion are of lesser medical significance. The quicker post-surgery mobilization of patients known from peridural endoscopic intervertebral disk surgery in comparison to the classical or microscopic surgery technique will be even more significant with the open access to the lumbar spine implementation and the multiple times longer access length.

[0017] The result is a negligent blood loss and minimum muscle trauma, since muscle fibers will not be severed but merely displaced. The exposed muscle fibers immediately close the access tunnel; bleeding or rough lesions of the muscle tissue are very rare. Trauma-related post-surgery pain is reduced significantly; mobilization of the patient will occur sooner. A simple and gentle dorsal stabilization option can be ensured.

[0018] Instrumentation of the thoracic spine is feasible monosegmental to bisegmental. However, a slightly higher position of the screw heads should be considered in order to avoid any conflict between the longitudinal connector and the spine section between the pedicle screws.

[0019] The invention will be explained in the following embodiment example.

[0020] **Fig.** 1 shows the geometric principle of the invented device structure;

[0021] **Fig.** 2 shows the principal structure of the invented device;

[0022] **Fig.** 3 shows the principal structure of the invented device according to **Fig.** 2 with bridge;

[0023] **Fig.** 4 shows the instrument for the insertion of pedicle screws; and

[0024] **Fig.** 5 shows the principal structure of the invented device according to **Fig.** 3 when used at a spine.

[0025] **Fig.** 1 shows the geometric principle of the invented device structure. It illustrates the principle of operation of the device for stereotactically guided percutaneous implantation of the pedicle screws' longitudinal connector. It is derived from the geometric principle of every triangle having a circumcircle, whereby its center point lies within the triangle and serves as intersection of the apothem and the triangle sides. The circumcircle crosses all corners of the triangle. In an isosceles triangle, the circumcircle's center point lies on the triangle's axis of symmetry. The sagittal bend of the lumbar spine describes a semi-circle or part of an oval. Measured at the entrance points of the two pedicle screws of one or more movement segments, these points are crossed by the circle. In geometrical terms, the longitudinal connector that connects the two screws is a circular arc with a definable radius and center point at a predetermined bend.

[0026] **Fig.** 2 shows the principal structure of the invented device without bridge; it illustrates the geometric connection between **Fig.** 1 and **Fig.** 3.

[0027] **Fig.** 3 shows the principal structure of the invented device with bridge. In this embodiment example, the device for stereotactically guided percutaneous implantation of the pedicle screws' longitudinal connector has a bridge with at least two attachments with infinitely variable spacing for mounting two equally long working cannulas which sit on the pedicle screw heads after the pedicle screws have been fastened. A swivel arm is provided in a pivot on the bridge above the variable attachments which has a mount at its free end for mounting an arched longitudinal connector that is provided for the longitudinal connection of the pedicle screws, whereby the pivot above the bridge is arranged in a way where the arched longitudinal connector at the free end of the swivel arm will move through both pedicle screw heads when the swivel arm is swiveled. Since the interpedicular distance is not constant, infinitely variable adjustment and locking of the cannula spacing is required. Any change of the interpedicular spacing results in a change of the angle between the cannulas, since the alignment of the freely movable screw heads must positively follow the bend of the defined longitudinal connector radius. In order to realize the geometric principle of an isosceles triangle in its circumcircle, the

working cannulas seated on the screw heads are movable and/or tiltable. The attachments are connected by gears which affect their uniform tilting during screw head spacing and angle changes and ensure that the geometric principles of an isosceles triangle are maintained. Once the carousel is seated on the pedicle screws, the pre-bent longitudinal connector swivels via the movable arm into the screw heads and is fastened with the inside nut.

[0028] Fig. 4 shows the instrument for the insertion of pedicle screws. A guideway is cut into the instrument's wall. The instrument will be introduced into the working cannula in order to ensure that the lateral screw holes and the cannula seated on the screw head, which also has a lateral opening in the area of the screw head, are positioned on top of each other. This ensures that the openings in the screw heads are moved in the direction of the incoming longitudinal connector. These procedures are performed on one side at the upper and lower screw. The actual device for stereotactically guided percutaneous implantation of the pedicle screws' connector will be placed on the implants which extend towards the outside (extracutaneous).

[0029] Fig. 5 shows the principal structure of the invented device according to **Fig.** 3 when used at a spine. Pedicle screws were recessed in two movement segments of the spine, where by the openings in the screw heads are aligned towards the incoming longitudinal connector with the assistance of the instrument for insertion of the pedicle screws. The longitudinal connector is located at the swivel arm of the device for stereotactically guided percutaneous implantation of the pedicle screws' longitudinal connector and will be swiveled towards the openings in the screw heads.

Patent Claims

1. Device for stereotactically guided percutaneous implantation of the longitudinal connectors of pedicle screws, **characterized by** a bridge with at least two attachments with infinitely variable spacing for mounting two equally long working cannulas which sit on the pedicle screw heads after the pedicle screws have been fastened, and by a swivel arm in a pivot on the bridge above the variable attachments which has a mount at its free end for a semi-circular longitudinal connector that is provided for the longitudinal connection of the pedicle screws, whereby the pivot above the bridge is arranged in a way where the semi-circular longitudinal connector at the free end of the swivel arm will move through both pedicle screw heads when the swivel arm is swiveled.
2. Device for stereotactically guided percutaneous implantation of the longitudinal connectors of pedicle screws according to Claim 1, characterized by the attachments being connected by gears which affect their uniform tilting during screw head spacing and angle changes and ensure that the geometric principles of an isosceles triangle are maintained.
3. Device for stereotactically guided percutaneous implantation of the longitudinal connectors of pedicle screws according to Claim 1 or 2, characterized by the pedicle screws being perforated polyaxial screws.
4. Instrument for the insertion of the pedicle screws, consisting of one cannula with lateral lamellae that are provided for insertion into the working cannula, and one guideway that is cut between the lamellae into the cannula wall.

See 5 Page(s) of drawings

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Drawing 1

Isosceles Triangle in a Circumcircle

A=A
X- Triangle / Circumcircle Center Point
YZ- Circular Arc
M- Axis of Symmetry

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Drawing 2

[Schwenkarm]
Swivel arm

[Langsträgerhalterung]
Longitudinal connector mount

[Längsträger]
Longitudinal connector

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Drawing 3

[Schwenkarm]
Swivel arm

[Brücke]
Bridge

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Drawing 4

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Drawing 5

[Wirbelsäule]
Spine

[Pedikelschrauben]
Pedicle screws